

Shaping the Future of Pediatric Formulation Development

Public Workshop

June 24-25, 2026

Agenda

Wednesday, June 24

Day 1

7:45 AM – 8:30 AM

Registration

Opening Session: Why Are We Here?

8:30 AM – 8:35 AM

Welcome & Workshop Objectives

Trupti Dixit, PhD, MBA

Workshop Program Chair, Independent Consultant, Dixit Consulting

8:35 AM – 9:05 AM

Pediatric Formulations: What is Needed?

John Alexander, PhD

Supervisory Physician, DPMH, ORDPURM, OND, CDER, FDA

9:05 AM – 9:35 AM

The Evolution of Pediatric Product Development: Progress, Remaining Gaps, and Future Directions

Joanna Koziara, PhD

Executive Director, Technical Development Strategy and Operations, Gilead;
Co-chair IQ Pediatric Working Group

Session 1A: Patient-Centricity

Session Leads: Dr. Trupti Dixit, Dr. Mona Khurana

Scope: Patient-centric product development in the context of pediatric formulation means using a user-focused approach that understands the physiological, developmental and psychological needs of the pediatric population that spans from neonates to adolescence. This translates into tailoring dosage forms to address factors such as dosing flexibility, taste-masking and swallowing abilities across this age group and ascertain that caregivers can deliver these medications where needed to ensure adherence to dosing regimen to impact health outcomes. This concept also applies to easing the burden of clinical studies and arriving at appropriate dosing regimens with minimal hardships on this vulnerable population. This session will present perspectives on some of these aspects to promote understanding and generate discussion on some of these key topics.

9:35 AM – 9:40 AM

Speaker Introductions

Mona Khurana, MD

Lead Physician, DPMH, ORDPURM, OND, CDER, FDA

9:40 AM – 10:10 AM

Pediatric Patient and Family Perspective

Patient and Family Representatives

International Children's Advisory Network (ICAN)

10:10 AM – 10:30 AM

Compounding 101: A Regulatory Framework

Dominic E. Markwordt, JD, MBA

Regulatory Counsel, OCQC, OC, CDER, FDA

10:30 AM – 10:45 AM

Break

10:45 AM – 11:05 AM

Pediatric Compounded Medication Safety: Examining Error-Related and Spontaneous Adverse Events

Shannon Glueck, PharmD

Branch Chief, DC II, Branch 6, OCQC, OC, CDER, FDA

11:05 AM – 11:25 AM

Welcome to the Jungle: Real World Challenges with Pediatric Dosage Forms

Rachel Meyers, PharmD

Clinical Professor, Ernest Mario School of Pharmacy, Rutgers University,
Cooperman Barnabas Medical Center

11:25 AM – 12:00 PM

Panel Discussion

Moderators:

Trupti Dixit, PhD, MBA

Mona Khurana, MD

Workshop Program Chair, Independent Consultant, Dixit Consulting

Lead Physician, DPMH, ORDPURM, OND, CDER, FDA

Panelists:

Patient and Family Representatives

Dominic E. Markwordt, JD, MBA

Shannon Glueck, PhD

Rachel Meyers, PharmD

International Children's Advisory Network (ICAN)

Regulatory Counsel, OCQC, OC, CDER, FDA

Branch Chief, CB 6, DC II, OCQC, OC, CDER, FDA

Clinical Professor, Ernest Mario School of Pharmacy, Rutgers University;

Pediatric Clinical Pharmacist, Cooperman Barnabas Medical Center

Alyssa Hager, PharmD, BCPPS

Department of Pharmacy Informatics, Children's National Hospital

12:00 PM – 1:00 PM **Lunch**

Session 2A: Formulation and Analytical Aspects of a Pediatric Dosage Form

Mini Tablets

Session Leads: Ms. Elizabeth Galella, Dr. David Tan

Scope: This session will focus on key aspects of developing mini tablets as a dosage form for pediatrics. This session will provide a forum to discuss acceptability of mini tablets across pediatric age groups, inconsistencies in nomenclature, manufacturing and packaging challenges and limitations, and strategies for identifying appropriate food vehicles.

1:00 PM – 1:05 PM	Speaker Introductions Elizabeth Galella, MS	Associate Director, Oral Product Development, Bristol-Myers Squibb
1:05 PM – 1:25 PM	Overview of the Mini Tablet Formulation with a Focus on Nomenclature Stuart Charlton, PhD	Director, Oral Product Development, Bristol Myers Squibb, UK
1:25 PM – 1:45 PM	Tablets and Drug Product Nomenclature LCDR Jibril Abdus-Samad, PharmD	Nomenclature and Labeling Policy Lead, COSS, OPPQ, OPQ, CDER, FDA
1:45 PM – 2:05 PM	Mini Tablet Manufacturing Challenges Katie Metzler, MS	Director, Vertex Pharmaceuticals
2:05 PM – 2:25 PM	Navigating Packaging Challenges for Mini Tablets Kirsten O'Brien, BS	Director, Packaging Development, Gilead Sciences
2:25 PM – 2:45 PM	Food Selection, Compatibility and Testing Strategies Anna Externbrink, PhD	Associate Principal Scientist, Analytical R&D, Merck
2:45 PM – 3:05 PM	Case Studies: Enteral Tube Administration of Mini Tablets Yemin Liu, PhD	Senior Principal Research Scientist, AbbVie Inc.
3:05 PM – 3:25 PM	Mini Tablet User Experience Smita Salunke, PhD	Chief Scientific Officer, EuPFI
3:25 PM – 3:40 PM	Break	
3:40 PM – 4:40 PM	Panel Discussion Moderators: Elizabeth Galella, MS David Tan, PhD Panelists: Stuart Charlton, PhD Katie Metzler, MS Kirsten O'Brien, BS LCDR Jibril Abdus-Samad, PharmD Anna Externbrink, PhD Yemin Liu, PhD Smita Salunke, PhD	Associate Director, Oral Product Development, Bristol-Myers Squibb Senior Director, Vertex Pharmaceuticals Inc. Director, Oral Product Development, Bristol Myers Squibb, UK Director, Vertex Pharmaceuticals Director, Packaging Development, Gilead Sciences Nomenclature and Labeling Policy Lead, COSS, OPPQ, OPQ, CDER, FDA Associate Principal Scientist, Analytical R&D, Merck Senior Principal Research Scientist, AbbVie Inc. Chief Scientific Officer, EuPFI
4:40 PM – 5:00 PM	Day 1 Summary	
5:00 PM – 6:30 PM	Networking/Posters	

Thursday, June 25

Day 2

7:30 AM – 8:00 AM

Registration

8:00 AM – 8:15 AM

Day 2 Introduction

Steve Hoag, PhD

Professor, Pharmaceutical Sciences; Director, Applied Pharmaceutics Lab,
University of Maryland-Baltimore

Session 2B: Formulation and Analytical Aspects of a Pediatric Dosage Form

Excipients for Pediatric Formulations

Session Leads: Dr. Steve Hoag, Dr. Anjali Agarwal, Dr. Sandip Tiwari, Dr. Smita Salunke

Scope: This session features presentations on the assessment of excipients for pediatric formulations, including tools such as the IID and ELSA, delivered by FDA experts. Industry perspectives are provided through talks on challenges and considerations in selecting excipients for pediatric products, including the use of the PERA tool. Additional insights focus on excipient needs for special populations—such as neonates. The program concludes with a breakout session on the PERA tool and a forward-looking panel discussion on future needs, research priorities, and regulatory challenges in pediatric excipient development.

8:15 AM – 8:20 AM

Speaker Introductions

Steve Hoag, PhD

Professor, Pharmaceutical Sciences; Director, Applied Pharmaceutics Lab,
University of Maryland-Baltimore

8:20 AM – 8:45 AM

Excipients in Pediatric Formulations: Evolution, Current Use, and Regulatory Considerations

Sandip Tiwari, PhD

Head of Technical Services, Pharma Solutions, BASF

8:45 AM – 9:15 AM

Safety of Excipients for Pediatric Formulation-Assessment, IID, and “ELSA” tool

April Braddy, PhD, RAC, SEP

Division Director, DB III, OB, OGD, CDER, FDA

9:15 AM – 9:45 AM

Experiences and Perspectives with Excipients When Reviewing Regulatory Submissions

Ndidi Nwokorie, MBBS

Medical Officer, DPMH, ORDPURM, OND, CDER, FDA

9:45 AM – 10:00 AM

Break

10:00 AM – 11:00 AM

Break Out Session: Industrial Perspective on Excipients in Pediatric Formulation Development

Anjali Agarwal, PhD

Smita Salunke, PhD

Executive Director, CMC & Product Supply, Novo Nordisk
Chief Scientific Officer, EuPFI

11:00 AM – 11:45 AM

Panel Discussion

Moderators:

Steve Hoag, PhD

Professor, Pharmaceutical Sciences; Director, Applied Pharmaceutics Lab,
University of Maryland-Baltimore

Panelists:

Sandip Tiwari, PhD

April Braddy, PhD, RAC, SEP

Ndidi Nwokorie, MBBS

Anjali Agarwal, PhD

Smita Salunke, PhD

Head of Technical Services, Pharma Solutions, BASF

Division Director, DB III, OB, OGD, CDER, FDA

Medical Officer, DPMH, ORDPURM, OND, CDER, FDA

Executive Director, CMC & Product Supply, Novo Nordisk

Chief Scientific Officer, EuPFI

11:45 AM – 12:45 PM

Lunch

Session 1B: Patient-Centricity

Session Leads: Dr. Trupti Dixit, Dr. Mona Khurana

Scope: Patient-centric product development in the context of pediatric formulation means using a user-focused approach that understands the physiological, developmental and psychological needs of the pediatric population that spans from neonates to adolescence. This translates into tailoring dosage forms to address factors such as dosing flexibility, taste-masking and swallowing abilities across this age group and also ascertain that caregivers can deliver these medications where needed to ensure adherence to dosing regimen to impact health outcomes. This concept also applies to easing the burden of clinical studies and arriving at appropriate dosing regimens with minimal hardships on this vulnerable population. This session will present perspectives on some of these aspects to promote understanding and generate discussion on some of these key topics.

12:45 PM – 12:50 PM

Speaker Introductions

Trupti Dixit, PhD, MBA

Independent Consultant, Dixit Consulting

12:50 PM – 1:20 PM

Caregiver Perspective: Acceptability of Pediatric Oral Dissolving Film in a Clinical Study

Adrie Bekker, PhD

Neonatologist, Tygerberg Children’s Hospital; Prof. of Pediatrics, Stellenbosch
University, Cape Town, South Africa

Lario Viljoen, PhD Sociobehavioural Lead, Desmond Tutu TB Centre, Department of Paediatrics and Child Health, Stellenbosch University, Cape Town, South Africa

1:20 PM – 1:40 PM **Formulation Challenges for Neonatal Dosage Form Development**
Karen Thompson, PhD Senior Principal Scientist, Preclinical Development, Merck

1:40 PM – 2:00 PM **Challenges in Dose and Dose Delivery Devices for Pediatric Formulations**
Tianyi (Tim) Zhang, PhD Human Factors Reviewer, DMEPA I, OMEPRM, OSE, CDER, FDA

2:00 PM – 2:30 PM **Panel Discussion**
Moderators: **Trupti Dixit, PhD, MBA** Workshop Program Chair, Independent Consultant, Dixit Consulting
Mona Khurana, MD Lead Physician, DPMH, ORDPURM, OND, CDER, FDA
Panelists: **Adrie Bekker, PhD** Neonatologist, Tygerberg Children's Hospital; Prof. of Pediatrics, Stellenbosch University, Cape Town, South Africa
Lario Viljoen, PhD Sociobehavioural Lead, Desmond Tutu TB Centre, Department of Paediatrics and Child Health, Stellenbosch University, Cape Town, South Africa
Karen Thompson, PhD Senior Principal Scientist, Preclinical Development, Merck
Tianyi (Tim) Zhang, PhD Human Factors Reviewer, DMEPA I, OMEPRM, OSE, CDER, FDA

Session 3: Imagining the Future of Pediatric Formulation Development

Session Lead: Ms. Erica Long

Scope: Since our last pediatric workshop in 2019, we have seen transformational innovations in drug delivery systems, the evolution of complex biologics, as well as new techniques for gene editing and gene therapy. Furthermore, recent advances in pediatric modeling/simulation, and in AI/ML methodologies are having a broad impact on drug discovery and development. In this session, we will briefly discuss these trends and how they will shape the future of developing better drugs and delivery systems for children.

2:30 PM – 2:35 PM **Speaker Introductions**
Erica Long, MEng Scientist, Pfizer, Inc.

2:35 PM – 2:55 PM **Trends in Pediatric Formulations and Delivery Systems**
Daniel Schaufelberger, PhD Adjunct Assistant Professor, John Hopkins, School of Medicine

2:55 PM – 3:15 PM **Microneedle-Based Biologics: A Next-Generation Platform for Pediatric Delivery**
Sonika Chibh, PhD Visiting Scientist, Koch institute for Integrative Cancer Research, MIT

3:15 PM – 3:35 PM **Trends in Pediatric Modeling and Simulation-What the Formulator Should Know**
Jon Collins, PhD Director, Clinical Pharmacology, ViV Healthcare Inc.

3:35 PM – 3:50 PM **Break**

Collaboration for Kids (across Academia, Health Authorities, Industry, and Non-profit Organizations)

Scope: This session will look towards establishing potential collaboration opportunities through shared understanding of the work done by various organizations such as industry, academia, philanthropic organizations or governments. The distinguished panel members from each of these organizations will share their perspectives through panel discussion. Workshop participants are encouraged to share their questions even ahead of time to enable productive, focused discussion on key topics as they relate to pediatric formulation development.

Discussion points: innovation, acceleration, coordination, international harmonization, incentives

3:50 PM – 3:55 PM **Panelist Introductions**
Trupti Dixit, PhD, MBA Workshop Program Chair, Independent Consultant, Dixit Consulting

3:55 PM – 4:30 PM **Panel Discussion**
Moderator: **Trupti Dixit, PhD, MBA** Workshop Program Chair, Independent Consultant, Dixit Consulting
Daniel Schaufelberger, PhD Adjunct Assistant Professor, John Hopkins, School of Medicine
Panelists: **John Alexander, PhD** Supervisory Physician, DPMH, ORDPURM, OND, CDER, FDA
James Cummins, Jr, PhD Chief, Preclinical Microbicide and Prevention Research Branch, Prevention Sciences Program, DAIDS, NIAID, NIH
Steve Hoag, PhD Professor, Pharmaceutical Sciences; Director, Applied Pharmaceuticals Lab, University of Maryland-Baltimore
Joanna Koziara, PhD Executive Director, Technical Development Strategy and Operations, Gilead;
Sandip Tiwari, PhD Co-chair IQ Pediatric Working Group
Head of Technical Services, Pharma Solutions, BASF

4:30 PM – 5:00 PM **Closing Remarks & Next Steps, Action Items**
Trupti Dixit, PhD Workshop Program Chair, Independent Consultant, Dixit Consulting

Daniel Schaufelberger, PhD
Steve Hoag, PhD

Adjunct Assistant Professor, John Hopkins, School of Medicine
Professor, Pharmaceutical Sciences; Director, Applied Pharmaceutics Lab,
University of Maryland-Baltimore